

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 8, 2012

DRAFT Questions to the Committee

- 1) **DISCUSSION:** Discuss the efficacy data of rilonacept for the prevention of gout flares.
 - a. Include a discussion of the effect of rilonacept on flare frequency and duration, and whether the observed treatment effect provides adequate justification for the use of rilonacept to prevent gout flares in a gout population that is not intolerant of or refractory to non-steroidal anti-inflammatory drugs (NSAIDs) and/or colchicine.
 - b. Include a discussion of the clinical applicability of the proposed indication, addressing whether the efficacy data support a treatment duration of 16 weeks.
- 2) **DISCUSSION:** Discuss the safety profile of rilonacept for the prevention of gout flares.
 - a. Include a discussion of the malignancy imbalance.
 - b. Include a discussion of the adequacy of the currently available 16-week safety database to support the proposed use.
- 3) **VOTE:** Are the available efficacy data adequate and supportive of approval of rilonacept for the prevention of gout flares during the initiation of uric acid-lowering therapy in adult patients with gout?
 - a. If not, what further efficacy data should be obtained?
- 4) **VOTE:** Are the available safety data adequate and supportive of approval of rilonacept for the prevention of gout flares during the initiation of uric acid-lowering therapy in adult patients with gout?
 - a. If not, what further safety data should be obtained?
- 5) **VOTE:** Do the efficacy and safety data support the approval of rilonacept 80 mg subcutaneously once weekly (following a 160 mg loading dose) for 16 weeks for the prevention of gout flares during the initiation of uric acid-lowering therapy in adult patients with gout?
 - a. If not, what further data should be obtained?